

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

DeLeys et al

Atty. Ref.: 2752-58

Divisional of Serial No.09/941,611

Group:

Filed: January 15, 2002

Examiner:

For: **SYNTHETIC ANTIGENS FOR THE DETECTION OF
ANTIBODIES TO HEPATITIS C VIRUS**

* * * * *

January 15, 2002

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

AMENDMENT

Preliminarily amend the above identified application as follows:

IN THE SPECIFICATION

Amend the specification as follows:

Page 1, line 1, insert the following paragraph:

--This application is a divisional of Application No. 09/941,611, filed August 30, 2001, which in turn is a divisional of Application No. 09/275,265, filed March 23, 1999, now U.S. Patent No. 6,287,761, which in turn is a continuation of Application No. 08/391,671 filed February 21, 1995, now U.S. Patent 5,922,532, which is a continuation of Application No. 07/920,286, filed October 14, 1992, abandoned, which is a 371 of PCT/EP91/02409, filed December 31, 1991, the entire content of which is hereby incorporated by reference herein.--

Delete the second and third full paragraphs (lines 6-11) on page 3 and insert the following in its place:

--Figures 1A - 1D show the amino acid sequences of the composite HCV_{HC-J1/CDC/CHI} (SEQ ID NO:23)

Figures 2A-2L show the antibody binding to individual peptides and various mixtures in an ELISA assay. Coating combinations used for Figures 2A - 2L are as follows:

1 : IX, 2 : XVIII, 3 : I, 4 : III, 5 : V, 6 : IX + XVIII, 7 : I + XVIII, 8 : I + III + IX, 9 : I + III + V + XVIII, 10 : I + III + V + IX, 11 : I + III + IX + XVIII, 12 : I + III + V + IX + XVIII.--

Page 5, delete the paragraphs spanning lines 19-26 and insert the following therefor:

--Peptide I, shown in SEQ ID NO:1, corresponds to amino acids 1 to 20 and has the amino acid sequence:

(I)

Y-Met-Ser-Thr-Ile-Pro-Lys-Pro-Gln-Arg-Lys-Thr-Lys-Arg-Asn-Thr-Asn-Arg-Arg-Pro-Gln-Z-X.

Peptide I, shown in SEQ ID NO:1, corresponds to amino acids 7 to 26 and has the amino acid sequence:--.

Page 6, delete the paragraph at line 1 and insert the following therefor:

--Of particular interest is the oligopeptide IIA, shown in SEQ ID NO:3, which has the sequence--.

Page 6, delete the paragraph at line 6 and insert the following therefor:

--Peptide III, shown in SEQ ID NO:4, corresponds to amino acids 13 to 32 and has the sequence:--.

Page 6, delete the paragraph at line 11 and insert the following therefor:

--Peptide IV, shown in SEQ ID NO:5, corresponds to amino acid 37 to 56 and has the sequence:--.

Page 6, delete the paragraph at line 16, and insert the following:

--Peptide V, shown in SEQ ID NO:6, corresponds to amino acids 49 to 68 and has the sequence:--.

Page 6, delete the paragraph spanning lines 21 and 22 and insert the following therefor:

--Peptide VI, shown in SEQ ID NO:7, corresponds to amino acid 61 to 80 and has the following sequence:--

Page 6, delete the paragraph at line 27 and insert the following therefor:

--Peptide VII, shown in SEQ ID NO:8, corresponds to amino acids 73 to 92 and has the sequence:--.

Page 7, delete the paragraph spanning lines 1 and 2 and insert the following therefore:

--Peptide VIII, shown in SEQ ID NO:9, corresponds to amino acids 1688 to 1707 and has the sequence:--.

Page 7, delete the paragraph spanning lines 7 and 8 and insert the following therefor:

--Peptide IX, shown in SEQ ID NO:10, corresponds to amino acids 1694 to 1713 and has the sequence:--.

Page 7, delete the paragraph spanning lines 13 and 14 and insert the following therefor:

--Peptide X, shown in SEQ ID NO:11, corresponds to amino acids 1706 to 1725 and has the sequence:--.

Page 7, delete the paragraph spanning lines 19 and 20 and insert the following therefor:

--Peptide XI, shown in SEQ ID NO:12, corresponds to amino acids 1712 to 1731 and has the sequence:--.

Page 7, delete the paragraph spanning lines 25 and 26 and insert the following therefor:

--Peptide XII, shown in SEQ ID NO:13, corresponds to amino acids 1718 to 1737 and has the sequence:--.

Page 8, delete the paragraph spanning lines 1 and 2 and insert the following therefor:

-- Peptide XIII, shown in SEQ ID NO:14, corresponds to amino acids 1724 to 1743 and has the sequence:--.

Page 8, delete the paragraph spanning lines 7 and 8 and insert the following therefor:

-- Peptide XIV, shown in SEQ ID NO:15, corresponds to amino acids 1730 to 1749 and has the sequence:--.

Page 8, delete the paragraph spanning lines 13 and 14 and insert the following therefor:

--Peptide XV, shown in SEQ ID NO:16, corresponds to amino acids 2263 to 2282 and has the sequence:--.

Page 8, delete the paragraph spanning lines 19 and 20 and insert the following therefor:

-- Peptide XVI, shown in SEQ ID NO:17, corresponds to amino acids 2275 to 2284 and has the sequence:--.

Page 8, delete the paragraph spanning lines 26 and 27 and insert the following therefor:

-- Peptide XVII, shown in SEQ ID NO:18, corresponds to amino acids 2287 to 2306 and has the sequence:--.

Page 9, delete the paragraph spanning lines 1 and 2 and insert the following therefor:

-- Peptide XVIII, shown in SEQ ID NO:19, corresponds to amino acids 2299 to 2318 and has the sequence:--.

Page 9, delete the paragraph spanning lines 7 and 8 and insert the following therefor:

-- Peptide XIX, shown in SEQ ID NO:20, corresponds to amino acids 2311 to 2330 and has the sequence:--.

Insert the attached Sequence Listing after the claims pages.

IN THE CLAIMS

Amend the claims as follows:

Delete claims 1-25, without prejudice.

Add the following claims:

--26. (new) A peptide consisting of at least 5 to less than 20 amino acids located in the region consisting of amino acids 1 to 20 of the HCV polyprotein of an HCV isolate which is capable of providing for immunological competition with at least one strain of HCV.

27. (new) A peptide consisting of at least 5 to less than 20 amino acids located in the region consisting of amino acids 7 to 26 of the HCV polyprotein of an HCV isolate which is capable of providing for immunological competition with at least one strain of HCV.

28. (new) A peptide consisting of at least 5 to less than 20 amino acids located in the region consisting of amino acids 13 to 32 of the HCV polyprotein of an HCV isolate which is capable of providing for immunological competition with at least one strain of HCV.

29. (new) A peptide consisting of at least 5 to less than 20 amino acids located in the region consisting of amino acids 37 to 56 of the HCV polyprotein of an HCV

isolate which is capable of providing for immunological competition with at least one strain of HCV.

30. (new) A peptide consisting of at least 5 to less than 20 amino acids located in the region consisting of amino acids 49 to 68 of the HCV polyprotein of an HCV isolate which is capable of providing for immunological competition with at least one strain of HCV.

31. (new) A peptide consisting of at least 5 to less than 20 amino acids located in the region consisting of amino acids 61 to 80 of the HCV polyprotein of an HCV isolate which is capable of providing for immunological competition with at least one strain of HCV.

32. (new) A peptide consisting of at least 5 to less than 20 amino acids located in the region consisting of amino acids 73 to 92 of the HCV polyprotein of an HCV isolate which is capable of providing for immunological competition with at least one strain of HCV.

33. (new) A method for the detection of antibodies to hepatitis C virus present in a body fluid comprising the steps of:

(a) contacting a body fluid of a person to be diagnosed with a peptide according to claim 26, and,

(b) detecting an immunological complex formed between antibodies in said body fluid and said peptide as an indication of the presence of antibodies to hepatitis C virus.

34. (new) A method for the detection of antibodies to hepatitis C virus present in a body fluid comprising the steps of:

(a) contacting a body fluid of a person to be diagnosed with a peptide according to claim 27, and,

(b) detecting an immunological complex formed between antibodies in said body fluid and said peptide as an indication of the presence of antibodies to hepatitis C virus.

35. (new) A method for the detection of antibodies to hepatitis C virus present in a body fluid comprising the steps of:

(a) contacting a body fluid of a person to be diagnosed with a peptide according to claim 28, and,

(b) detecting an immunological complex formed between antibodies in said body fluid and said peptide as an indication of the presence of antibodies to hepatitis C virus.

36. (new) A method for the detection of antibodies to hepatitis C virus present in a body fluid comprising the steps of:

(a) contacting a body fluid of a person to be diagnosed with a peptide according to claim 29, and,

(b) detecting an immunological complex formed between antibodies in said body fluid and said peptide as an indication of the presence of antibodies to hepatitis C virus.

37. (new) A method for the detection of antibodies to hepatitis C virus present in a body fluid comprising the steps of:

(a) contacting a body fluid of a person to be diagnosed with a peptide according to claim 30, and,

(b) detecting an immunological complex formed between antibodies in said body fluid and said peptide as an indication of the presence of antibodies to hepatitis C virus.

38. (new) A method for the detection of antibodies to hepatitis C virus present in a body fluid comprising the steps of:

(a) contacting a body fluid of a person to be diagnosed with a peptide according to claim 31, and,

(b) detecting an immunological complex formed between antibodies in said body fluid and said peptide as an indication of the presence of antibodies to hepatitis C virus.

39. (new) A method for the detection of antibodies to hepatitis C virus present in a body fluid comprising the steps of:

- (a) contacting a body fluid of a person to be diagnosed with a peptide according to claim 32, and,
- (b) detecting an immunological complex formed between antibodies in said body fluid and said peptide as an indication of the presence of antibodies to hepatitis C virus.

40. (new) A kit for the detection of anti-hepatitis C virus antibodies in a body fluid, comprising: a peptide according to claim 26, and

a means for detecting an immunological complex formed between said peptide and said antibodies.

41. (new) A kit for the detection of anti-hepatitis C virus antibodies in a body fluid, comprising: a peptide according to claim 27, and

a means for detecting an immunological complex formed between said peptide and said antibodies.

42. (new) A kit for the detection of anti-hepatitis C virus antibodies in a body fluid, comprising: a peptide according to claim 28, and

a means for detecting an immunological complex formed between said peptide and said antibodies.

43. (new) A kit for the detection of anti-hepatitis C virus antibodies in a body fluid, comprising: a peptide according to claim 29, and
a means for detecting an immunological complex formed between said peptide and said antibodies.

44. (new) A kit for the detection of anti-hepatitis C virus antibodies in a body fluid, comprising: a peptide according to claim 30, and
a means for detecting an immunological complex formed between said peptide and said antibodies.

45. (new) A kit for the detection of anti-hepatitis C virus antibodies in a body fluid, comprising: a peptide according to claim 31, and
a means for detecting an immunological complex formed between said peptide and said antibodies.

46. (new) A kit for the detection of anti-hepatitis C virus antibodies in a body fluid, comprising: a peptide according to claim 32, and
a means for detecting an immunological complex formed between said peptide and said antibodies.

47. (new) A peptide according to claim 26 wherein said amino acids spanning positions 1 to 20 of the HCV polyprotein is SEQ ID NO: 1.

48. (new) A peptide according to claim 27 wherein said amino acids spanning positions 7 to 26 of the HCV polyprotein is SEQ ID NO: 2.

49. (new) A peptide according to claim 28 wherein said amino acids spanning positions 13 to 32 of the HCV polyprotein is SEQ ID NO: 4.

50. (new) A peptide according to claim 29 wherein said amino acids spanning positions 37 to 56 of the HCV polyprotein is SEQ ID NO: 5.

51. (new) A peptide according to claim 30 wherein said amino acids spanning positions 49 to 68 of the HCV polyprotein is SEQ ID NO: 6.

52. (new) A peptide according to claim 31 wherein said amino acids spanning positions 61 to 80 of the HCV polyprotein is SEQ ID NO: 7.

53. (new) A peptide according to claim 32 wherein said amino acids spanning positions 73 to 92 of the HCV polyprotein is SEQ ID NO: 8.--

REMARKS

Claims 1-25 have been canceled, without prejudice. Claims 26-53 are pending.

DeLeys et al
Divisional of Serial No. 09/941,611

The specification has been amended to be consistent with amendments made in the parent application Serial No. 09/941,611. No new matter has been added.

Copies of the formal drawings filed and accepted in the grand-parent application Serial No. 09/275,265 (and filed in the parent application Serial No. 09/941,611). No amendments in this regard are believed to be required however the Office is requested to advise the undersigned if otherwise.

The specification has been amended to include the attached paper copy of the Sequence Listing. The attached paper copy of the Sequence Listing is the same as the paper and computer-readable copy of the Sequence Listing filed in the parent application Serial No. 09/941,611. No new matter has been added. The Office is requested to use the computer-readable copy of the Sequence Listing from the parent application Serial No. 09/941,611 and grand-parent application Serial No. 09/275,265 for the present application. A separate Request in this regard is attached.

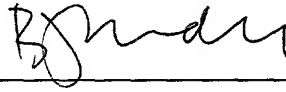
An early and favorable Action on the merits in the above-identified application is requested.

DeLeys et al
Divisional of Serial No. 09/941,611

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: _____



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MARKED UP SPECIFICATION AND CLAIMS

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--Figures 1A - 1D show the amino acid sequences of the composite HCV_{HC}.

J1/CDC/CHI (SEQ ID NO:23)

Figures 2A-2L show the antibody binding to individual peptides and various mixtures in an ELISA assay. Coating combinations used for Figures 2A - 2L are as follows:

1 : IX, 2 : XVIII, 3 : I, 4 : III, 5 : V, 6 : IX + XVIII, 7 : I + XVIII, 8 : I + III + IX, 9 : I + III + V + XVIII, 10 : I + III + V + IX, 11 : I + III + IX + XVIII, 12 : I + III + V + IX + XVIII.--

Page 5, delete the paragraphs spanning lines 19-26 and insert the following therefor:

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* * * * *

January 15, 2002

Assistant Commissioner for Patents
Washington, DC 20231

SUBMISSION OF FORMAL DRAWINGS

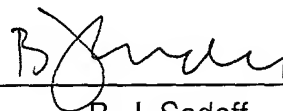
Sir:

Enclosed herewith are eight (8) sheets of formal, inked drawings for the above-identified application.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: _____



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